

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

JOHN THUMANN,

Plaintiff,

V.

ALEX AZAR, in his capacity as Secretary of
the United States Department of Health and
Human Services,

Defendant.

•
•

•
•

•
•

•
•

•
•

•
•

•
•

Case No. 20-cv-125

Judge Timothy S. Black

PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT

Pursuant to FED.R.CIV.P. 56, Plaintiff John Thumann respectfully submits this motion for summary judgment, requesting an order reversing the denial of Mr. Thumann's claim for Medicare coverage for the life-prolonging treatment known as Tumor Treatment Field Therapy (TTFT), and holding that the Secretary of the U.S. Department of Health and Human Services is barred by collateral estoppel from denying Mr. Thumann's claims for Medicare coverage at issue. As explained in the attached Memorandum in Support, it is fundamentally unjust and a waste of personal and judicial resources to force Mr. Thumann to repeatedly litigate this same issue.

Dated: August 24, 2020

Respectfully submitted,

/s/ Allen L. Rutz

Allen L. Rutz, Trial Attorney (0069388)
Vorys, Sater, Seymour and Pease LLP
52 East Gay Street, P.O. Box 1008
Columbus OH 43216-1008
Tel: (614) 464-5644
Fax: (614) 719-5023
alrutz@vorys.com

OF COUNSEL:

James C. Pistorino

PARRISH LAW OFFICES

788 Washington Road

Pittsburgh, PA 15228

Telephone: (412) 561-6250

james@dparrishlaw.com

Attorneys for Plaintiff

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

JOHN THUMANN,

Plaintiff,

V.

ALEX AZAR, in his capacity as Secretary of
the United States Department of Health and
Human Services,

Defendant.

[illegible]

Case No. 20-cv-125

Judge Timothy S. Black

MEMORANDUM IN SUPPORT OF PLAINTIFF'S
MOTION FOR SUMMARY JUDGMENT

This is an administrative review case, the resolution of which turns solely on an issue of law. As detailed in the Complaint and herein, Mr. Thumann is suffering from a particularly lethal form of brain cancer, glioblastoma multiforme (GBM). Even with the tumor treatment field therapy (TTFT) that is the subject of the coverage dispute, the two-year survival rate remains well below 50%.

Mr. Thumann has been forced to repeatedly litigate the issue of whether TTFT is a covered Medicare benefit for him, as well as the sub-issues of whether TTFT is “medically reasonable and necessary,” “safe and effective,” and not “experimental or investigational”. Mr. Thumann has received prior decisions from Administrative Law Judges (ALJs) finding in his favor on all these issues. The Secretary did not appeal those decisions and they have now become final. Nevertheless, the Secretary continues to force Mr. Thumann to re-litigate the identical issues during the time he should be spending with family and focusing on his recovery.

This has to stop.

Mr. Thumann is not alone in having to constantly re-litigate for coverage of TTFT, with at least 6 other similar cases pending in other U.S. jurisdictions. Mr. Thumann thus moves herein for a ruling that collateral estoppel bars the Secretary from denying him coverage for TTFT treatment. While this case could also be decided on the grounds that the Secretary's decision is arbitrary and capricious and not supported by substantial evidence, a decision on those grounds alone would only address the one claim at issue, and would have no broader applicability to either Mr. Thumann or others with GBM that are caught in a litigation trap with the Secretary.

I LEGAL BACKGROUND FOR ADMINISTRATIVE COLLATERAL ESTOPPEL

Collateral estoppel (*i.e.*, “issue preclusion”) is a venerable common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine of collateral estoppel, “once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation.” *Montana v. United States*, 440 U.S. 147, 153-54 (1979). Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

Collateral estoppel applies when: 1) the precise issue was raised and actually litigated in the prior proceedings; 2) the determination of the issue was necessary to the outcome of the prior proceedings; 3) the prior proceedings resulted in a final judgment on the merits; and 4) the party against whom estoppel is sought had a full and fair opportunity to litigate the issue in the prior

proceeding. *See, e.g., Georgia-Pacific Consumer Products, LP v. Four-U-Packaging, Inc.*, 701 F.3d 1093, 1098 (6th Cir. 2012).

As detailed below, Mr. Thumann has litigated multiple claims before the Secretary, often in parallel/concurrent proceedings. Parallel/concurrent litigation is common. Where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) (“The first to reach final decision can affect the other ... through rules of claim and issue preclusion (res judicata and collateral estoppel)[.]”). In other words, a later-filed or decided case that reaches finality first may have preclusive effect on an earlier-filed, but still on-going litigation.

Because of the unique posture of the United States as a litigant, the Supreme Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S. v. Mendoza*, 464 U.S. 154 (1984). As a result, only a party to a prior proceeding with the government can assert collateral estoppel against the government. Here, Mr. Thumann is not seeking to collaterally estop the Secretary with respect to coverage for TTFT claims filed by any person other than himself. Instead, Mr. Thumann only contends that he should not have to re-litigate the same coverage issues against the Secretary that have already been finally and conclusively determined in his favor.

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it

which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

(internal citations omitted). *See also B & B Hardware, Inc. v. Hargis Industries, Inc.*, 135 S.Ct. 1293, 1302-3 (2015) (confirming that administrative decisions can be a basis for issue preclusion).

As set forth in *Astoria*, there is a presumption that common law principles (including collateral estoppel) apply to administrative decisions where an agency is acting in a “judicial capacity.” *Astoria*, 501 U.S. at 108 (“where a common-law principle is well established, as are the rules of preclusion, the court may take it as a given that Congress has legislated with an expectation that the principle will apply except where a statutory purpose to the contrary is evident.”). A party asserting that collateral estoppel does not apply bears the burden of establishing the presumption has been overcome. *See Green v. Block Laundry Machine Co.*, 490 U.S. 504, 521 (1989) (“has the burden of showing that the legislature intended such a change.”).

In order to overcome the presumption of the common law, the party so asserting must demonstrate that Congress evidenced an intent to do so. *Astoria*, 501 U.S. at 109-110 (common law applies “absent clearly expressed congressional intent to the contrary”); *U.S. v. Texas*, 507 U.S. 529, 535 (1993) (“an expression of legislative intent to supplant”); *Green*, 490 U.S. at 521 (must show “legislature intended such a change”). Moreover, in order to overcome the presumption, a statute must “speak directly” to the common law issue. *See Texas*, 507 U.S. at 534 (“In order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law.”, internal citations and quotations omitted). Statutes which are

compatible with the pre-existing practice of the common law do not overcome the presumption. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994).

The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed.App'x. 542 (6th Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ' work determination); *Drummond v. Comm'r of Social Security*, 126 F.3d 837, 841-43 (6th Cir. 1997) (SSA collaterally estopped by prior ALJ work determination); *Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7th Cir. 1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. United States*, 570 F.2d 1311, 1321-23 (7th Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *C & N*, 953 F.Supp.2d at 912-14 (defendant collaterally estopped by prior TTAB proceeding); *Islam v. U.S. D.H.S.*, 136 F.Supp.3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination). *See also DeWall Enterprises, Inc. v. Thompson*, 206 F.Supp.2d 992, 1001 (D. Neb. 2002) ("The Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit.").

II FACTUAL BACKGROUND

A. Tumor Treatment Field Therapy (TTFT)

Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. With earlier forms of treatment before TTFT, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living. Individuals with recurrent GBM have a life expectancy of six months.¹

More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor

¹ "Recurrent" GBM means that the tumor has increased by 25% since the last treatment.

cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.

In ground-breaking papers published in the Journal of the American Medical Association (JAMA)² in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.³

As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all major private insurers cover TTFT. TTFT extends GBM patients' lives, in some cases, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a Level One recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.⁴ Further, TTFT is FDA approved.

The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune system. The Optune system is rented on a monthly basis. Once a Medicare patient suffering from GBM is prescribed the Optune system, they will have monthly

² The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journals in the United States and the world.

³ See Stupp, *et al.*, "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); Stupp, *et al.*, "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

⁴ This is the highest recommendation given to less than 10% of cancer treatments.

claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their lives.

B. The Medicare Appeals Process

People suffering from GBM and being treated with TTFT will have multiple claims for Medicare coverage. Typically, these claims will be submitted every one to three months to reflect their continued usage of the TTFT device. Each claim for Medicare coverage concerns only the one to three months at issue for that claim.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process that can (and typically does) take more than a year. At issue at each stage of the process is whether the claim is a Medicare covered benefit/is medically reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928.⁵ If the claim is denied, the beneficiary can request “redetermination.” *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, the beneficiary can request “reconsideration.” *See* 42 C.F.R. §§ 405.960-978.

If the claim is still denied, the Secretary is required to provide “hearings” for appeals to the “same extent” as is provided for in Social Security hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the “hearing” by administrative law judges (ALJs). *See* 42 C.F.R. §§ 405.1000-1058. At a minimum, in the case

⁵ At issue in this case are claims submitted under “Original Medicare” (*i.e.*, “Medicare Part B”). Accordingly, the regulatory citations herein are those applicable to Part B claims. Medicare Part C (*i.e.*, “Medicare Advantage Plans”) is governed by similar/identical regulations. *See* 42 C.F.R. §§ 422.560-626.

where the beneficiary is represented by counsel, the hearings are adversarial. In such a case, the Secretary's representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a "contractor" to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008 and 405.1010.

In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018), object to the timing of the hearing (42 C.F.R. § 405.1020), object to the issues before the ALJ (42 C.F.R. § 405.1024); object to the assigned ALJ (42 C.F.R. § 405.1026); present evidence in the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. § 405.1037). After the hearing, the ALJ issues a written decision that includes findings of fact, conclusions of law, and the reasons for the decision and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046.

Like the beneficiary, if the Secretary is dissatisfied with the ALJ's decision, the Secretary can appeal to the Medicare Appeals Council ("Council"). *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary chooses to participate in the hearing, the Secretary can appeal an ALJ's decision on so-called "own motion" review. *See* 42 C.F.R. § 405.1110.

Finally, if the beneficiary is dissatisfied with a decision from the Council, they can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(g)).

Although the statutes and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.,* 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before they can seek relief in a federal court.

C. Mr. Thumann

John Thumann is a 78-year old husband of more than 50 years to wife Terri, father of four, and grandfather to nine. A native of Cincinnati, Ohio, Mr. Thumann has both a B.S.B.A. and an M.B.A. (finance) degree from Xavier University. Mr. Thumann served in the U.S. Army (artillery) and Ohio National Guard for six years. Thereafter, Mr. Thumann enjoyed a 40-year career in accounting and finance for several Ohio based companies before retiring in 2008. In his free time, Mr. Thumann enjoys being with his family and is an avid sportsman (fishing, hunting, hiking, and golf). In addition, Mr. Thumann is active in his church and has been a volunteer with the Saint Vincent de Paul Society for a number of years.

In 2018, Mr. Thumann was diagnosed with GBM and, after undergoing surgery and chemo-radiation, Mr. Thumann was prescribed the Optune TTFT device.

1. Gates' August 19, 2019 Decision Granting Coverage:

Mr. Thumann sought Medicare coverage for his TTFT device for the months of November 2018-January 2019 and his claim was denied initially, denied on redetermination, and denied on reconsideration. Thereafter, through his counsel Parrish Law Offices, Mr. Thumann requested an ALJ hearing.

On July 29, 2019, ALJ Timothy Gates held a hearing at which neither CMS nor a contractor appeared but Mr. Thumann's representative (Debra Parrish) did. Thereafter, on August 19, 2019, ALJ Gates issued a decision favorable to Mr. Thumann in ALJ Appeal No. 1-8651191426. *See* Certified Administrative Record (CAR) at 10-18 (Doc. #6-2 at 10-18). Among a number of findings supporting TTFT coverage, Judge Gates found:

- 1) "Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in GBM brain tumors compared with traditional standards of care alone." *See* CAR at 11 (Doc. #6-2 at 11);

- 2) “in this case, [Mr. Thumann] has provided evidence which clearly establishes TTFT is safe and effective for its intended use in patients with newly-diagnosed and recurrent GCM.” *See* CAR at 17 (Doc. #6-2 at 17);
- 3) “The record further shows that TTFT has broad acceptance in the medical community as a safe and effective treatment for GBM.” *See* CAR 17 (Doc. #6-2 at 17);
- 4) “I find that TTFT is not experimental in nature.” *See* CAR 18 (Doc. #6-2 at 18);
- 5) “The FDA approval of TTFT, the overwhelming medical research evidence, and the written declaration of the Supplier’s VP of Health Policy that the treatment is safe and effective in extending the lives of patients who have been newly diagnosed or have recurrent glioblastoma support the finding that the devices at issue is reasonable and necessary and covered by Medicare.” *Id.*;
- 6) “Therefore, I find that the record clearly establishes that the device is medically reasonable and necessary to treat [Mr. Thumann’s] condition.” *Id.*; and
- 7) “The electronic stimulation device (E0766) furnished to [Mr. Thumann] on Dates of Service is reasonable and necessary under Section 1862 of the Act and is covered by Medicare.” *Id.*

The Secretary did not appeal Judge Gates’ decision and it became final no later than October 19, 2019.

2. Bartlett’ November 5, 2019 Decision Granting Coverage:

Mr. Thumann sought Medicare coverage for his TTFT device for the months of February-May 2019 and his claims were denied initially, denied on redetermination, and denied on reconsideration. Thereafter, on September 25, 2019, through his counsel Parrish Law Offices, Mr. Thumann requested an ALJ hearing and submitted a pre-hearing brief.

When neither CMS nor its contractor responded to the Notice of Hearing, pursuant to 42 C.F.R. § 405.1038(a), ALJ Jeannie Bartlett ruled on the papers and issued a decision favorable to Mr. Thumann in ALJ Appeal No. 3-8787160676 on November 5, 2019. *See* CAR 26-34 (Doc. #6-2 at 25-34).

Among a number of findings supporting TTFT coverage, Judge Bartlett found:

- 1) “In this case, [Mr. Thumann] has provided sufficient evidence that established TTFT is safe and effective for patients with newly-diagnosed and recurrent GBM.” *See* CAR 30 (Doc. #6-2 at 30);
- 2) “A consensus exists based on the published, peer-reviewed literature which demonstrates the effectiveness of TTFT for newly-diagnosed GBM. The Optune device has shown a significantly improved medical outcome, demonstrating its use is not experimental or investigational.” *See* CAR 32 (Doc. #6-2 at 32); and
- 3) “Therefore, the record clearly establishes that [Mr. Thumann] is entitled to coverage for the electric stimulation cancer treatment (E0766) provided to [Mr. Thumann] on February 16, 2019, March 16, 2019, April 16, 2019, and May 16, 2019.” *See* CAR 33 (Doc. #6-2 at 33).

The Secretary did not appeal Judge Bartlett’s decision and it became final no later than January 5, 2020.⁶

3. MacDougall’ September 5, 2019 Decision Denying Coverage:

Mr. Thumann sought Medicare coverage for his TTFT device for the months of August-October 2018 and his claims were denied initially, denied on redetermination (*see* CAR 465-67, Doc. #6-3 at 65-67), and denied on reconsideration (*see* CAR 443-53, Doc. #6-3 at 43-53). On March 27, 2019, through his counsel, Parrish Law Offices, Mr. Thumann requested an ALJ hearing and submitted a pre-hearing brief.

On July 10, 2019, ALJ Bruce MacDougall held a hearing at which neither CMS nor a contractor appeared but Mr. Thumann’s representative (Debra Parrish) did. Thereafter, on

⁶ In addition to the favorable decisions from ALJs Gates and Bartlett, on June 3, 2020, Mr. Thumann also received a favorable decision from ALJ Eli Bruch for the months of June-August 2019. Copy attached as Exhibit A. The Secretary did not appeal Judge Bruch’s decision and it became final no later than August 3, 2020. This Court may properly take judicial notice of this most recent decision, which addresses the same issues as the decisions of ALJ Gates and Bartlett. *See Opoka v. INS*, 94 F.3d 392 (7th Cir. 1996) (court took judicial notice of later proceedings to vacate and remand a Board of Immigration Appeals decision, the review of which was limited to the record before it). Nevertheless, because the decisions of ALJs Gates and Bartlett are sufficient for the present purposes and in an effort to minimize the issues, Mr. Thumann believes that this Court’s decision may properly rest solely on the decisions from ALJs Gates and Bartlett.

September 5, 2019, ALJ MacDougall issued a decision denying coverage in ALJ 1-8411066311. *See* CAR 52-60, Doc. #6-2 at 52-60). Contrary to the findings of ALJs Gates and Bartlett, ALJ MacDougall found that he could not even decide whether TTFT was reasonable and necessary for Mr. Thumann because the very evidence that established that fact would also show that the Local Coverage Determination⁷ on which the denial was based was invalid and ALJ MacDougall held that he did not have that authority. Thus, because Mr. Thumann presented evidence that his TTFT treatment was reasonable and necessary, ALJ MacDougall held that he could not decide that the treatment was reasonable and necessary. This was so, though: “The quality of the record developed and the arguments presented by [Mr. Thumann] are outstanding.” *See* CAR 58 (Doc. #6-2 at 58).

Thus, contrary to ALJs Gates and Bartlett, ALJ MacDougall held: “the services here are not reasonable and necessary and there is no coverage to treat [Mr. Thumann’s] glioblastoma multiforme.” *See* CAR 58 (Doc. #6-2 at 58). Further, ALJ MacDougall held: “Medicare Part B coverage and payment does not exist for the Optune TTFT (tumor treatment field therapy) electrical stimulation device (HCPS Code E0766) provided to [Mr. Thumann] on monthly rental periods beginning August 16, 2018, September 16, 2018, and October 16, 2018.” *See* CAR 59 (Doc. #6-2 at 59).

Thereafter, Mr. Thumann timely appealed ALJ MacDougall’s decision to the Medicare Appeals Council on September 10, 2019. *See* CAR 38-44 (Doc. #6-2 at 38-44). As detailed therein, Mr. Thumann specifically brought ALJ’s Gates prior favorable decision to the Council’s

⁷ A Local Coverage Determination (LCD) is a policy of coverage/non-coverage created by a contractor to Medicare. While an LCD is controlling as to the initial levels of claim consideration, a LCD is not binding on either ALJs or the Medicare Appeals Council when they consider appeals of claim denials. *See* 42 C.F.R. § 405.1062(a) (“not bound by LCDs”).

attention and argued that the Secretary was barred by collateral estoppel from denying coverage. Pursuant to 42 U.S.C. § 1395ff(d)(2), the Council was required to issue a ruling within 90 days. When no decision was received by that date, on December 31, 2019, Mr. Thumann requested “escalation” pursuant to 42 C.F.R. § 405.1132 bringing both ALJ Gates and Bartlett’s prior favorable decisions as well as authority on collateral estoppel from the Supreme Court to the Council’s attention. *See* CAR 5 (Doc. #6-2 at 5). Subsequently, the Council did not issue a decision which authorized the filing of this suit in district court. *See* CAR 1-2 (Doc. #6-2 at 1-2).

III DISCUSSION

As a result of the separate and final decisions finding TTFT to be a covered benefit/”medically reasonable and necessary” for Mr. Thumann, the Secretary should be collaterally estopped from issuing denials on the same grounds that were rejected by those other final decisions. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should reverse the Secretary’s denial, order coverage, and remand this case with instructions to the Secretary to effectuate the Court’s decision.

A. The Department Was Acting in a Judicial Capacity When It Issued the Prior Decisions

Out of an abundance of caution, Mr. Thumann addresses the issue of whether the Department was acting in a “judicial capacity” when it issued the prior decisions and whether the procedures adopted by the Secretary provided the Secretary with a fair opportunity to present his case. There can be little dispute on either point.

As an initial matter, pursuant to the statute, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence in conducting the hearings. *See* 42 U.S.C. § 405(b). The Secretary has further issued regulations confirming the “judicial” and adversarial nature of the hearings and providing the Secretary a fair opportunity to present his case.

As detailed above, at a minimum when the beneficiary is represented, “hearings” before the Secretary are conducted by Administrative Law Judges and the Secretary (through his representatives) has an opportunity to submit evidence, object to the timing of the hearing, object to the issues at the hearing, object to the assigned ALJ, present evidence in the form of documents and witnesses (including through subpoenas), take discovery, cross-examine witnesses, and present argument. *See* 42 C.F.R. §§ 405.1018, 1020, 1024, 1026, 1036, and 1037. After the hearing, the ALJ issues a written decision including findings of fact and conclusions of law and the reasons for the decision. *See* 42 C.F.R. § 405.1046. Further, if the Secretary is dissatisfied with the ALJ’s decision, the Secretary can appeal to the Council using the procedures of 42 C.F.R. §§ 405.1100-1140 (appeal as a party) or 42 C.F.R. § 405.1110 (“own motion review”).

Thus, in making the prior decisions on which estoppel is based, the Secretary (through his ALJ) was acting in a judicial capacity and the Secretary had a fair opportunity to present his case.

As detailed above, the Secretary chose not to take advantage of these opportunities. That is of no moment because collateral estoppel is only concerned with whether the party against whom collateral estoppel is invoked had a fair opportunity to present their case, not whether they chose to take advantage of that opportunity. *See, e.g., Meyer*, 36 F.3d at 1379-80; *EZ Loader*, 746 F.2d at 377-78. Further, it would make little sense to force Mr. Thumann to repeatedly carry his burden in the litigation as well as the burdens placed on the courts/judicial bodies, merely because the Secretary chose to make no effort in this regard. Such an approach would be contrary the very purposes of collateral estoppel.⁸

⁸ Simply as an example, because the Secretary has forced Plaintiffs in this case and others to repeatedly litigate the issue of TTFT coverage, so far, Plaintiffs have been the subject of seven ALJ decisions on the exact same issue.

B. Collateral Estoppel

Collateral estoppel should conclusively bar the Secretary from re-litigating the issue of TTFT coverage for Mr. Thumann.

1. The Precise Issue Was Raised and Actually Litigated in the Prior Proceedings

At issue in any Medicare coverage litigation is whether the device/service is a Medicare covered benefit for the beneficiary. This conclusion involves the sub-issues of whether the device/service is “medically reasonable and necessary” for the beneficiary and the further sub-issue of whether the device/service is “safe and effective.”⁹ *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) (any item which is not “medically reasonable and necessary” is excluded from coverage). Thus, whenever a coverage decision has determined that a device/service is a Medicare covered benefit, it has necessarily determined that the device/service is medically reasonable and necessary for that particular beneficiary as well as that the device/service is “safe and effective.”

As noted above, both ALJ Gates and Bartlett found that TTFT was a Medicare covered benefit (and the sub-issues of whether it is “medically reasonable and necessary”/“safe and effective”) for Mr. Thumann. *See, e.g.*, CAR 18 (Doc. #6-2 at 18) (“clearly establishes that the device is medically reasonable and necessary”, “is covered by Medicare”) (for ALJ Gates); CAR 33 (Doc. #6-2 at 33) (“clearly establishes that [Mr. Thumann] is entitled to coverage”) (for ALJ Bartlett).

Those are the same issues that ALJ MacDougall addressed which the Secretary is collaterally estopped from contesting. Thus, as indicated above, contrary to ALJs Gates and

⁹ Under Medicare’s rules, it can never be “medically reasonable and necessary” to provide a device/service that is not “safe and effective.”

Bartlett, ALJ MacDougall held that TTFT is not “medically reasonable and necessary” and that Medicare coverage does not exist for TTFT. *See* CAR 58-59 (Doc. #6-2 at 58-59).

To the extent that the Secretary alleges that the issues are not identical because each decision relates to particular months of treatment, there is no merit to that claim. It is well settled that the test for determining whether facts/issues are the same between two decisions for collateral estoppel purposes is “materiality.” That is, facts/issues are the same unless they are materially different with respect to the conclusions reached (*i.e.*, “changed circumstances”). *See, e.g., Montana v. U.S.*, 440 U.S. 147, 159 (1979) (“changes in facts essential to a judgment will render collateral estoppel inapplicable”); *Bernstein v. Bankert*, 733 F.3d 190, 226 (7th Cir. 2013) (“identical in all material aspects”); *Scooper Dooper, Inc., v. Kraftco Corp.*, 494 F.2d 840, 846 (3rd Cir. 1974). There is no material difference with regard to coverage between November 2018-May 2019 (when ALJs Gates and Bartlett found coverage) and October 2018 (when ALJ MacDougall held there was no coverage).

Moreover, unlike a default, Mr. Thumann was put to his burden of proof before ALJs Gates and Bartlett. *See, e.g.,* CAR at 13 (Doc. #6-2 at 13) (“The burden of proving each element of a Medicare claim lies with [Mr. Thumann] by preponderance of the evidence (*i.e.*, is satisfied by submitting sufficient evidence in accordance with program requirements.” *citing statutes and regulations*). *See Restatement (Second) of Judgments* § 27 cmt. d (1982) (“When an issue is properly raised, by the pleadings or otherwise, and is submitted for determination and is determined, the issue is actually litigated.”); *Matter of Garner*, 56 F.3d 677, 680 (5th Cir. 1996) (defendant who answered Complaint but did not otherwise appear, bound by collateral estoppel because plaintiff put to burden of proof). Thus, in the present case, the matter was “litigated on the merits”/“actually litigated” because Mr. Thumann was put to his burden of proof and the risks

and expense of meeting that burden. The Secretary's decision not to appear at the ALJ hearing only means that the Secretary relied on Mr. Thumann having to meet that burden of proof as the Secretary's only defense.

The precise issues addressed in ALJ MacDougall's decision were raised and actually litigated in the proceedings before ALJs Gates and Bartlett.

2. The Determination of the Issue Was Necessary to the Outcome of the Prior Proceedings

Of course, the base issue in each Medicare coverage dispute is whether an item/service is a Medicare covered benefit. Thus, the determination on that issue was necessary to the outcome of the proceedings before ALJs Gates and Bartlett (on which collateral estoppel is based) just as it was for the decision of ALJ MacDougall.

Likewise, because there could be no determination that TTFT was a Medicare covered benefit for Mr. Thumann without a determination that TTFT was "medically reasonable and necessary" for him, that determination was essential to the final judgment. Likewise, because whether something is "medically reasonable and necessary" is itself dependent on whether it is "safe and effective", again, that finding was essential to the final judgment.

Thus, determination of the same issues on which preclusion is sought was necessary to the outcome of the prior proceedings before ALJs Gates and Bartlett.

3. The Prior Proceedings Resulted in a Final Judgment on the Merits

The favorable decisions of ALJs Gates and Bartlett are final decisions by ALJs within the jurisdiction of the Secretary's Department itself. That the Secretary did not appeal the adverse judgments of ALJs Gates and Bartlett and the fact that they have become final is also beyond dispute. *See* 70 Fed.Reg. 36386-7 (June 23, 2005) ("The ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by

the Medicare Appeals Council[.]”); 42 C.F.R. § 405.1102 (“... a written request for a Council review within 60 calendar days ...”). *See also Smith v. Berryhill*, 139 S.Ct. 1765, 1775-76 (2019) (under APA, action is “final” if it: 1) marks the consummation of the agency’s decisionmaking process; and 2) is one by which rights have been determined or from which legal consequences will flow). Thus, the third factor for collateral estoppel is fully established for Mr. Thumann.

4. The Party Against Whom Estoppel is Invoked Had a Full and Fair Opportunity to Litigate the Issue in the Prior Proceeding

Here, there can be little doubt that the Secretary had a full and fair opportunity to litigate the issues in the prior proceedings. As indicated, Mr. Thumann was represented in the cases before both ALJ Gates and Bartlett. Thus, pursuant to 42 C.F.R. §§ 405.1008 and 405.1010, the Secretary had the full rights of a litigant to present his case. That the Secretary chose not to take advantage of his opportunities to litigate is of no moment because the standard is only whether the Secretary had “a full and fair *opportunity* to litigate” and the Secretary did.

5. Other Comments

The fact that ALJ Bartlett’s decision of November 5, 2019 (on which collateral estoppel may be based) came *after* the decision of ALJ MacDougall of September 5, 2019, is of no moment. As indicated, when there is concurrent/parallel litigation, whichever decision reaches finality first may give rise to collateral estoppel against an earlier, but still on-going, litigation. *See, e.g., Adkins*, 779 F.3d at 484. Once the Secretary elected to allow the favorable decision of ALJ Bartlett become final, he should be estopped from continuing to litigate that same issue in all pending and future claims by the same Plaintiff. By contrast, the decision of ALJ MacDougall is subject to this appeal and is thus not final. Accordingly, the Secretary should be estopped from denying that TTFT is a Medicare covered benefit for Mr. Thumann (as well as the sub-issue of whether TTFT is “medically reasonable and necessary”) to treat his GBM condition.

Nevertheless, the issue may be avoided entirely because ALJ Gates' decision of August 19, 2019, is final and came before ALJ MacDougall's decision of September 5, 2019.

C. The Decision At Issue Should Be Reversed and Coverage Ordered

Once this Court properly applies collateral estoppel against the Secretary with respect to the issue of whether TTFT is a covered benefit/is "medically reasonable and necessary" for Mr. Thumann, the decision at issue should be reversed. The decision denying coverage was premised solely on the conclusion that TTFT was not "medically reasonable and necessary" for Mr. Thumann. That is, there was no other basis for the denial of coverage (*e.g.*, the beneficiary passed away). Thus, if the Secretary is collaterally estopped from re-litigating that issue, then there is no reason that coverage can/should be denied.

Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court can modify or reverse the Secretary's decisions "with or without remanding the cause for a rehearing." If the Secretary is collaterally estopped from denying coverage to Mr. Thumann in Appeal No. 1-8411066311, then there is no need or reason for further review by the Secretary and coverage should be ordered.

III. CONCLUSION

The Secretary should be collaterally estopped from denying that TTFT is a covered Medicare benefit and "medically reasonable and necessary" for Mr. Thumann. Mr. Thumann has sustained his burden of proving coverage multiple times and should not be tormented by repeated litigation.

The decisions at issue in this case should be reversed and coverage of Mr. Thumann's claim ordered.

Dated: August 24, 2020

Respectfully submitted,

/s/ Allen L. Rutz

Allen L. Rutz, Trial Attorney (0069388)
Vorys, Sater, Seymour and Pease LLP
52 East Gay Street, P.O. Box 1008
Columbus OH 43216-1008
Tel: (614) 464-5644
Fax: (614) 719-5023
alrutz@vorys.com

OF COUNSEL:

James C. Pistorino
PARRISH LAW OFFICES
788 Washington Road
Pittsburgh, PA 15228
Telephone: (412) 561-6250
james@dparrishlaw.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of August, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access the filing through the Court's electronic system.

/s/ Allen L. Rutz

Allen L. Rutz (0069388)
Counsel for Plaintiff